

REMARKS

Reconsideration is requested for claims 1-52. Favorable action is requested for new claim 53.

Claim 19 was rejected under 35 U.S.C. 112, second paragraph, on formal grounds. Claim 19 has been amended to address the grounds for rejection and withdrawal of the rejection is cordially urged.

Claims 1, 4-5, 10, 15-18, 20, 23-26, 28, 31-35, 41, 44-45, and 50-52 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,558,733 to *Hossainy*. *Hossainy* discloses stent 10 comprising a plurality of filaments 22 and interconnecting elements 24 in which one or more microdepots or pores 30 for carrying substances are formed. The filaments 22 and interconnecting elements 24 may be straight, sinusoidal, V-shaped, or may have other shapes. The depots 30 are not through-openings and have a depth D1 from about 10% to 90% of the thickness of the of the filament or interconnecting element in which they are formed. *See, e.g., Col. 5, lines 36-55.* It is noted that a depth greater than about 65% may compromise the structural integrity and mechanical functionality of the stent.

Claim 1, from which claims 2-9 and 31-32 depend, as amended, defines an expandable medical device for delivery of a beneficial agent, the device comprising a substantially cylindrical device which is expandable from a cylinder having a first diameter to a cylinder having a second diameter, the substantially cylindrical device comprising a plurality deformable members and non-deformable members, a first plurality of openings formed in the substantially cylindrical device containing a first beneficial agent for delivery to tissue, wherein the first openings are positioned on first and second ends of the cylindrical device, and a second plurality of openings formed in the substantially cylindrical device containing a second beneficial agent

for delivery to tissue, wherein the second openings are positioned on a central portion of the cylindrical device between the first and second ends, and wherein the second beneficial agent is different than the first beneficial agent. The first openings and the second openings are positioned on the non-deformable members.

By providing a substantially cylindrical device comprising a plurality of deformable members and non-deformable members, it is possible to control the manner in which the device expands from the first diameter to the second diameter by limiting deformation to the deformable members. At the same time, deformation of the first openings and the second openings that might adversely affect the introduction of drugs in the openings can be limited.

Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members and does not disclose providing depots only in one of the filaments or the interconnecting members. Because the filaments and interconnecting members can be curved, sinusoidal, or the like, it appears to be anticipated that the filaments and the interconnecting members are expected to deform during expansion from a smaller to a larger diameter.

In view of the differences between claim 1 and *Hossainy*, it is respectfully submitted that claim 1 and the claims dependent therefrom, including claims 2-9 and 31-32, are not anticipated by and define patentably over *Hossainy*. Withdrawal of the rejection is cordially urged.

Claim 10, from which claims 11-16 and 33-34 depend, as amended, defines a tissue supporting device comprising a tissue supporting device body configured to support a bodily lumen, the tissue supporting device comprising deformable and non-deformable members, a first beneficial agent contained in first openings in the tissue supporting device for delivery to tissue, wherein the first openings are positioned on first and second ends of the device body, and a

second beneficial agent contained in second openings in the tissue supporting device for delivery to tissue, wherein the second openings are positioned on a central portion of the device body between the first and second ends. The first openings and the second openings are positioned in the non-deformable members.

By providing a tissue supporting device comprising a plurality of deformable members and non-deformable members, it is possible to control deformation of the device by limiting deformation to the deformable members. At the same time, deformation of the first openings and the second openings that might adversely affect the introduction of drugs in the openings can be limited.

Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members and does not disclose providing depots only in one of the filaments or the interconnecting members.

In view of the differences between claim 10 and *Hossainy*, it is respectfully submitted that claim 10 and the claims dependent therefrom, including claims 11-16 and 33-34, are not anticipated by and define patentably over *Hossainy*. Withdrawal of the rejection is cordially urged.

Claim 17, from which claims 18-19 depend, as amended, defines an expandable medical device for delivery of a beneficial agent. The device comprises a device body which is expandable from an initial configuration to an expanded configuration defining a cylinder having end holes at opposite ends of the device, a side hole in the device body between the opposite ends and having a center axis substantially perpendicular to a longitudinal axis of the device body and configured to accommodate a bifurcation in a lumen, a first plurality of openings formed in the device body containing a first beneficial agent for delivery to tissue at the

expanded configuration, wherein the first openings are formed in an area surrounding the side hole, and a second plurality of openings formed in the body device in an area away from the side hole.

Hossainy does not disclose a combination of features including a side hole having a center axis substantially perpendicular to a longitudinal axis of the device body. Holes at the ends stent and the lumen itself do not define a side hole as defined in claim 17.

In view of the differences between claim 17 and *Hossainy*, it is respectfully submitted that claim 17 and the claims dependent therefrom are not anticipated by and define patentably over *Hossainy*. Withdrawal of the rejection is cordially urged.

Claim 20, from which claims 21-24 depend, as amended, defines a method of reducing restenosis in a body passageway, the method comprising positioning a tissue supporting device comprising deformable and non-deformable members in a body passageway to support the tissue, the tissue supporting device containing a first and a second beneficial agent in openings positioned in the non-deformable members in the device, and delivering the first beneficial agent to tissue at locations adjacent ends of the tissue supporting device and the second beneficial agent to tissue between the ends of the device to reduce restenosis.

By positioning a tissue supporting device comprising deformable and non-deformable members in a body passageway to support the tissue, with a first and a second beneficial agent in openings positioned in the non-deformable members in the device, the possibility of improper introduction of the beneficial agent due to deformation of an opening is reduced.

Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members and does not disclose providing depots only in one of the filaments or the interconnecting members.

In view of the differences between claim 20 and *Hossainy*, it is respectfully submitted that claim 20 and the claims dependent therefrom, including claims 21-24, are not anticipated by and define patentably over *Hossainy*. Withdrawal of the rejection is cordially urged.

Claim 25, from which claims 26-28 and 35 depend, as amended, defines an expandable medical device for delivery of a beneficial agent. The device comprises a substantially cylindrical device which is expandable from a cylinder having a first diameter to a cylinder having a second diameter, the substantially cylindrical device comprising deformable and non-deformable members, a first plurality of openings formed in the substantially cylindrical device containing the beneficial agent in a first concentration, and a second plurality of openings formed in the substantially cylindrical device containing the beneficial agent in a second concentration, wherein the first and second openings are arranged to deliver a uniform distribution of a drug to the tissue of a body passageway. The first openings and the second openings are positioned in the non-deformable members.

Hossainy does not disclose that the filaments are more or less deformable than the interconnecting members and does not disclose providing depots only in one of the filaments or the interconnecting members.

In view of the differences between claim 25 and *Hossainy*, it is respectfully submitted that claim 25 and the claims dependent therefrom, including claims 26-28 and 35, are not anticipated by and define patentably over *Hossainy*. Withdrawal of the rejection is cordially urged.

Claim 41, from which claims 42-53 depend, defines a tissue supporting device comprising a generally cylindrical tissue supporting device body configured to support a bodily lumen, a plurality of first through openings in the tissue supporting device body, wherein the first

openings contain a first beneficial agent, and a plurality of second through openings in the tissue supporting device body, wherein the second openings contain a second beneficial agent.

The depots 30 in *Hossainy* are not through openings, and *Hossainy* teaches away from the use of through openings on the grounds that too deep of an opening will reduce the structural integrity of the filament or interconnecting element. Col. 5, lines 51-53.

In view of the differences between claim 41 and *Hossainy*, it is respectfully submitted that claim 41 and the claims dependent therefrom, including claims 42-53, are not anticipated by and define patentably over *Hossainy*. Withdrawal of the rejection is cordially urged.

Claims 2-3, 6, 11, 14, 19, 21-22, 27, 42-43, and 46 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Hossainy* in view of U.S. Patent No. 6,699,281 to *Vallana et al.* *Vallana et al.* is cited as disclosing implanting drugs of different concentrations in a stent. *Vallana et al.*, however, cures none of the defects of the independent claims from which claims 2-3, 6, 11, 14, 19, 21-22, 27, 42-43, and 46 depend, namely claims 1, 10, 17, 20, 25, and 41. For at least the reasons discussed above with regard to those claims, it is respectfully submitted that claims 1, 10, 17, 20, 25, and 41 and the claims dependent therefrom, including claims 2-3, 6, 11, 14, 19, 21-22, 27, 42-43, and 46, define patentably over *Hossainy* in view of *Vallana et al.* Withdrawal of the rejection of these claims is cordially urged.

In addition, claim 27 depends from claim 25, which recites that the first and second openings are arranged to deliver a uniform distribution of a drug to the tissue of a body passageway. Claim 27 recites that a volume of the first openings per unit of surface area of the expanded device is greater than a volume of the second openings per unit of surface area and the first concentration is less than the second concentration to achieve the uniform distribution of the drug. *Vallana et al.*, at Col. 8, lines 15-30, discloses a differentiated levels of concentration

along the length of the stent, and does not disclose providing a uniform distribution of a drug.

Accordingly, any combination of *Hossainy* and *Vallana et al.* would not have resulted in the structure defined in claim 27. For at least this additional reason, it is respectfully submitted that claim 27 defines patentably over *Hossainy* in view of *Vallana et al.*

Claims 7-8, 12, and 47-48 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Hossainy* in view of U.S. Application Publication 2005/0278016 to *Welsh et al.* *Welsh et al.* is cited as disclosing using paclitaxel as a beneficial agent. *Welsh et al.*, however, cures none of the defects of the independent claims from which claims 7-8, 12, and 47-48 depend, namely claims 1, 10, and 41. For at least the reasons discussed above with regard to those claims, it is respectfully submitted that claims 1, 10, and 41 and the claims dependent therefrom, including claims 7-8, 12, and 47-48, define patentably over *Hossainy* in view of *Welsh et al.* Withdrawal of the rejection of these claims is cordially urged.

In addition, *Welsh et al.* is also cited as supporting a rejection of claims 7 and 47, which recite a third beneficial agent coated on a stent and cites paragraph [0144] in support of this position. Paragraph [0144] only asserts that it is possible to provide biocompatible coatings such as lubricious coatings on the stent, not that a beneficial agent is coated on a stent. Moreover, none of the cited references discloses or suggests combining beneficial agents in first and second openings on a stent, together with a third beneficial agent coated on the stent.

It is respectfully submitted that claims 7 and 47 patentably define over *Hossainy* in view of *Welsh et al.* in view of these additional shortcomings. Withdrawal of the rejection of these claims is cordially urged.

Claims 9, 13, and 49 were rejected under 35 U.S.C. 103(a) as being unpatentable over *Hossainy* in view of U.S. Patent Application Publication 2002/0007209 to *Schreeder et al.*

Schreeder et al. is cited as disclosing using rapamycin as a beneficial agent. *Schreeder et al.* however, cures none of the defects of the independent claims from which claims 9, 13, and 49 depend, namely claims 1, 10, and 41. For at least the reasons discussed above with regard to those claims, it is respectfully submitted that claims 1, 10, and 41 and the claims dependent therefrom, including claims 9, 13, and 49, define patentably over *Hossainy* in view of *Schreeder et al.* Withdrawal of the rejection of these claims is cordially urged.

It is respectfully submitted that all of the pending claims, claims 1-53, are in condition for allowance. Allowance is cordially urged.

To the extent that the applicant does not respond to a particular comment in the Official Action, the applicant does not intend by this to indicate acquiescence in or agreement with the comment. To the extent that any extensions of time are necessary in connection with this application it is requested that there be a standing petition for extension of time and that any additional fees that are required, or refunds due, in connection with this or any other paper filed in connection with this application be charged to Deposit Account 503100.

If the Examiner is of the opinion that a telephone conference would be helpful in resolving any outstanding issues, the Examiner is urged to contact the undersigned.

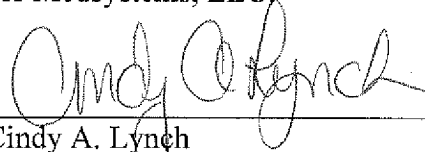
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Respectfully submitted,

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